DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Randox Laboratories, Ltd.
c/o Dr. Pauline Armstrong
55 Diamond Road, Crumlin County
Antrim, United Kingdom BT29 4QY

Re: k092272
Trade/Device Name: Methadone Assay
Regulation Number: 21 CFR 862.3620
Regulation Name: Methadone test system
Regulatory Class: II
Product Code: DJR, DKB, DIF
Dated: November 2, 2010
Received: November 4, 2010

NOV 18 2010

Dear Dr. Armstrong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K092272

NOV 18 2010

Indication for Use

510(k) Number (if known): k092272

Device Name: METHADONE ASSAY, MULTIDRUG CALIBRATOR SET AND MULTIDRUG CONTROLS LEVEL 1 & 2

Indication For Use:

Randox Methadone Assay

The Randox Laboratories Ltd. Methadone Assay is an in vitro diagnostic test for the qualitative and semi-quantitative detection of Methadone in human urine. The cut off for both the qualitative and semi-quantitative modes of the assay is 300ng/ml for methadone. The Randox Methadone Assay has been developed for use on the Cortex analysers, which includes the Daytona™ and the Imola™. This in vitro diagnostic device is intended for prescription use only.

The semi-quantitative mode is for purposes of

(1) enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as GCMS

or

(2) permitting laboratories to establish quality control procedures.

This assay provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatograph/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

Randox Multidrug Calibrator Set

The Randox Multidrug Calibrator Set consists of liquid calibrators containing Oxazepam and Methadone. There are 5 levels of calibrator. They have been developed for use in the calibration of Benzodiazepine (Oxazepam) and Methadone assays on the Cortex analysers, which includes the Daytona™ and the Imola™. This in vitro diagnostic device is intended for prescription use only. .

Randox Multidrug Controls, Level 1 & 2

The Randox Multidrug Controls, level 1 and 2 are liquid controls containing Oxazepam and Methadone. There are 2 levels of controls. They have been developed for use in the quality control of Benzodiazepine and Methadone assays on the Cortex analysers, which includes the Daytona™ and the Imola™. This in vitro diagnostic device is intended for prescription use only.

Prescription Use ✓ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K092272